Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
SAIBER LLC
One Gateway Center, 10th Floor
Newark, New Jersey 07102-5311
(973) 622-3333 (telephone)
(973) 286-2465 (facsimile)

Of Counsel:
Deepro R. Mukerjee
Lance A. Soderstrom
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, NY 10022-2585
Telephone: (212) 940-6330
Facsimile: (212) 940-8776
deepro.mukerjee@kattenlaw.com
lance.soderstrom@kattenlaw.com

Jitendra Malik, Ph.D.
Alissa Pacchioli
KATTEN MUCHIN ROSENMAN LLP
550 S. Tryon Street, Suite 2900
Charlotte, NC 28202-4213
Tel: (704) 444-2000
jitendra.malik@kattenlaw.com
alissa.pacchioli@kattenlaw.com

Attorneys for Plaintiff Mylan Specialty L.P.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN SPECIALTY L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
AUROBINDO PHARMA USA INC.,	)	***Document Filed Electronically***
	)	
Defendant.	)	
	)	
	)	

COMPLAINT

Plaintiff Mylan Specialty L.P. ("Mylan" or "Plaintiff"), by their attorneys, for their Complaint against Defendant Aurobindo Pharma USA Inc. ("Aurobindo" or "Defendant") alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 6,702,997 ("the '997 patent") arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*. This action relates to Abbreviated New Drug Application ("ANDA") No. 211888, filed by Aurobindo with the United States Food and Drug Administration ("FDA") for approval to market a generic version of AccuNeb® (albuterol sulfate EQ 0.021 % and EQ 0.042% base solution for inhalation product) prior to the expiration of the '997 patent.

THE PARTIES

2. Plaintiff Mylan Specialty L.P. is a company having a principal place of business at 781 Chestnut Ridge Road, 3rd Floor, Morgantown, West Virginia, 26505.

3. On information and belief, Defendant Aurobindo Pharma USA Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520-1401. On information and belief, Aurobindo Pharma USA Inc. developed and owns ANDA No. 211888.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 28 U.S.C. §§ 2201 and 2202.

5. Aurobindo Pharma USA Inc. is a corporation with its principal place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520-1401 and therefore is subject to the personal jurisdiction of this court.

6. Venue is proper in the District of New Jersey pursuant to 28 U.S.C. § 1400(b) because Aurobindo Pharma USA Inc. has committed acts of infringement and has a regular and established place of business in the judicial district. On information and belief, Aurobindo Pharma USA Inc., *inter alia*, developed and/or otherwise contributed to the development and filing of ANDA No. 211888 in the judicial district.

THE PATENT-IN-SUIT

7. The '997 patent, titled "Albuterol inhalation solution, system, kit and method for relieving symptoms of pediatric asthma," was duly and legally issued by the U.S. Patent and Trademark Office ("USPTO") on March 9, 2004. A true and correct copy of the '997 patent is attached as Exhibit A.

8. As set forth in greater detail in the '997 patent, the claims of the '997 patent, incorporated by reference herein, are directed to, *inter alia*, an albuterol inhalation solution, system, kit and method for relieving bronchospasm in children suffering from asthma.

9. Mylan Specialty L.P. is the assignee of the '997 patent.

10. Mylan Specialty L.P. is the holder of approved New Drug Application No. 020949 for albuterol sulfate EQ 0.021 % and EQ 0.042% base solution for inhalation product (the "AccuNeb® NDA").

11. AccuNeb® is indicated for relief of bronchospasm in patients 2 to 12 years of age with asthma (reversible obstructive airway disease). The approved usage of AccuNeb® is described in the AccuNeb® Prescribing Information.

12. The '997 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as covering AccuNeb® and its approved uses.

ACTS GIVING RISE TO THIS ACTION

13. In a letter dated September 6, 2018, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Notice Letter"), Aurobindo notified Mylan Specialty L.P. that it had submitted ANDA No. 211888 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed albuterol sulfate EQ 0.021 % and EQ 0.042% base solution for inhalation product (the "ANDA Product"), as a generic version of AccuNeb® in/into the United States, prior to the expiration of the '997 patent.

14. In the Notice Letter, Aurobindo notified Plaintiff that ANDA No. 211888 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '997 patent is invalid, unenforceable and/or not infringed by the ANDA Product ("Paragraph IV Certification"). The Notice Letter also offered Mylan Specialty L.P. confidential access to ANDA No. 211888 on terms and conditions set forth in an "Offer of Confidential Access" ("Aurobindo Offer").

15. After receiving the Aurobindo Offer, Plaintiff has sought from Aurobindo a copy of ANDA No. 211888, for the purpose of evaluating the ANDA Product in light of the '997 patent's claims, Plaintiff has been unable to obtain such information reasonably in advance of the expiration of the 45-day statutory deadline for filing suit.

16. On information and belief, the active ingredient of the ANDA Product is albuterol sulfate, which is the same active ingredient in AccuNeb® and the same active ingredient used in the compositions and methods of use described in one or more claims of the '997 patent.

17. On information and belief, Aurobindo asserts in ANDA No. 211888 that the ANDA Product is bioequivalent to AccuNeb®, refers to and relies upon the AccuNeb® NDA, and contains data that, according to Aurobindo, demonstrate the bioequivalence of the ANDA Product to AccuNeb®.

18. On information and belief, Aurobindo is seeking approval to market the ANDA Product for the same approved indication as AccuNeb®.

19. On information and belief, Aurobindo is seeking approval to market the ANDA Product for relief of bronchospasm in patients 2 to 12 years of age with asthma (reversible obstructive airway disease).

20. Aurobindo had knowledge of the '997 patent when it submitted and filed ANDA No. 211888.

21. On information and belief, Aurobindo intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product in/into the United States promptly upon receiving FDA approval and prior to the expiration of the '997 patent.

22. On information and belief, Aurobindo intends to and will actively induce infringement of one or more claims of the '997 patent upon receiving FDA approval of ANDA No. 211888 and prior to the expiration of the '997 patent.

23. On information and belief, Aurobindo will commercially manufacture, use, offer for sale, and/or sell the ANDA Product throughout the United States, import the ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the '997 patent.

24. On information and belief, Aurobindo will knowingly accompany the ANDA Product with prescribing information that will contain instructions for use that substantially copy the instructions for AccuNeb®.

25. On information and belief, Aurobindo's prescribing information for the ANDA Product will instruct users to administer the ANDA Product for relief of bronchospasm in patients 2 to 12 years of age with asthma (reversible obstructive airway disease).

26. On information and belief, Aurobindo has knowledge and/or an expectation that the ANDA Product will be used in accordance with its prescribing information.

27. On information and belief, Aurobindo knows that the prescribing information that will accompany the ANDA Product will induce and/or contribute to others using the ANDA Product in the manner set forth in the prescribing information.

28. On information and belief, Aurobindo knows that the ANDA Product is especially made or adapted for use in a way that would infringe the '997 patent, and is not suitable for substantial non-infringing use. On information and belief, Aurobindo knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the '997 patent, including without limitation claim 1 of the '997 patent.

29. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Mylan and Aurobindo with respect to infringement of the '997 patent.

30. This action is being commenced within 45 days of receipt of the Notice Letter.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 6,702,997

31. Mylan repeats and realleges the allegations of paragraphs 1-30 as if fully set forth herein.

32. Aurobindo's submission of ANDA No. 211888 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the ANDA Product in/into the United States prior to the expiration of the '997 patent constitutes infringement of one or more claims of the '997 patent under 35 U.S.C. § 271(e)(2)(A), including without limitation claim 1.

33. Aurobindo had knowledge of the '997 patent when it submitted ANDA No. 211888. Aurobindo's infringement has been, and continues to be, deliberate.

34. Plaintiff will be substantially and irreparably harmed if Aurobindo's infringement of the '997 patent is not enjoined. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment that Aurobindo has infringed one or more claims of the '997 patent by the filing of ANDA No. 211888;

(b) A judgment that Aurobindo's manufacturing, using, selling, offering for sale, and/or importing the ANDA Product in/into the United States will infringe one or more claims of the '997 patent;

(c) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 211888 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '997 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(d) A judgment under 35 U.S.C. § 271(e)(4)(B) providing injunctive relief against Aurobindo, whether alone or through a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the ANDA Product;

(e) A permanent injunction restraining and enjoining Aurobindo, whether alone or through a subsidiary company, from making, using, selling, offering for sale, and/or importing the ANDA Product or any pharmaceutical composition as claimed in the '997 patent in/into the United States, or practicing any methods as claimed in the '997 patent, or from actively inducing or contributing to the infringement of any claim of the '997 patent, until after the expiration of the '997 patent, inclusive of any extension(s) to the patent term;

(f) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(g) Costs and expenses in this action; and

(h) Such further and other relief as this Court may deem just and proper.

Date: October 22, 2018

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Mylan Specialty L.P.

/s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
One Gateway Center, 10th Floor
Newark, NJ 07102-5311
Telephone: (973) 622-3333
Facsimile: (973)-286-2465

Of Counsel:
Deepro R. Mukerjee
Lance Soderstrom
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, NY 10022
Telephone: (212) 940-6330
deepro.mukerjee@kattenlaw.com
lance.soderstrom@kattenlaw.com

Jitendra Malik, Ph.D.
Alissa Pacchioli
KATTEN MUCHIN ROSENMAN LLP
550 S. Tryon Street, Suite 2900
Charlotte, NC 28202-4213
Tel: (704) 444-2000
jitendra.malik@kattenlaw.com
alissa.pacchioli@kattenlaw.com

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Mylan Specialty L.P. hereby certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: October 22, 2018

s/ Arnold B. Calmann
Arnold B. Calmann

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Mylan Specialty L.P. hereby certifies that Mylan Specialty L.P. seeks injunctive relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: October 22, 2018

s/ Arnold B. Calmann
Arnold B. Calmann